



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Impact of Pharmacovigilance Systems

4th industry stakeholder platform - operation of EU pharmacovigilance legislation – 12 June 2015

Almath Spooner, PRAC
Peter Arlett, EMA
Xavier Kurz, EMA
Jacoline Bouvy, EMA
Marie-Helene Pinheiro, EMA



An agency of the European Union



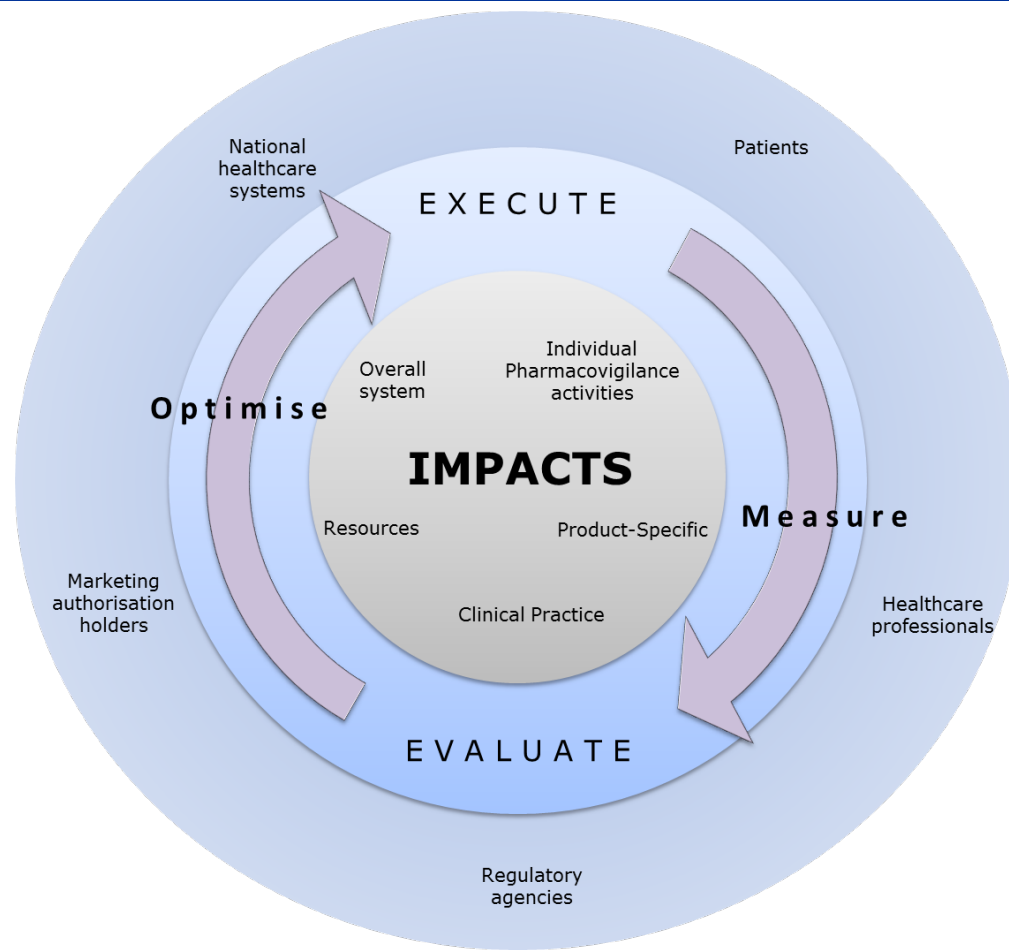


Disclaimer

The strategy on impact evaluation of pharmacovigilance Systems is under development and may change following consultation of EMA committees

Approach

- Health-focused
- Science-based
- Leverage ongoing work
 - Academia
 - Industry
- Prioritisation key tools and methods





Impact Evaluation

- Key element of the approach is the (bi-)annual measurement of:
 - Pharmacovigilance activities
 - System outputs
 - Stakeholder engagement
 - Patients, Healthcare professionals, Industry, NCAs
 - Effectiveness regulatory actions
 - Resources



Data to be collected for evaluation:

PhV system outcome measure	Components
Regulatory actions	<ul style="list-style-type: none">• SmPC changes• Educational material to advice to modify/change behaviour of patients/HCPs• DHPCs• Restrictions of indications• Withdrawals• Suspensions/revocations
Effectiveness of regulatory actions	<ul style="list-style-type: none">• Changes in the behaviour of patients resulting from regulatory communications regarding marketed products• Changes in the behaviour of HCPs resulting from regulatory communications regarding marketed products
Stakeholder engagement	<ul style="list-style-type: none">• Engagement of patients and HCPs in the pharmacovigilance system and in regulatory communications.
Resources	<ul style="list-style-type: none">• Possible survey



Moving forward

- Report on PhV tasks: this year
- 2018: report on impact of pharmacovigilance (outcomes)
- Development of strategy for impact evaluation with PRAC
- Collaborate with industry on development of tools
- Set-up of virtual interface with industry Stakeholders
 - Explore what existing data sources and activities might provide required data
 - Provide input in development of possible survey



Virtual interphase group

- Two members from interested EU industry stakeholders organisation
- Intends to provide input on:
 - Existing initiatives and activities that could be utilised for impact evaluation
 - Development of possible survey
- Nominations to Patricia.kaniki@ema.europa.eu, by end of June 2015